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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,112	11/20/2003	Johannes Bartholomaus	785-011574-US(PAR)	8885

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EXAMINER	
PERREIRA, MELISSA JEAN	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/718,112	BARTHOLOMAUS ET AL.	
	Examiner	Art Unit	
	Melissa Perreira	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/01/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 contains the trademark/trade name Avicel®, Blanose®, CMC-Na C300P®, Frimulsion BLC-5®, etc. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe viscosity-increasing agent and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claim 1-11, 18, 21, 23-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Alaux et al. (WO/002000/033835).

Alaux et al. (WO/2000/033835) teaches of a zolpidem or salt thereof controlled-release dosage form. The first phase or immediate phase induces the immediate sleep and is from 0-30 min while the second phase or prolonged release is between 2-6 hours (p1, last paragraph; p2, paragraph 2 and 8). The pellet or tablet prepared from spherical granules or pellets may be incorporated into a multilayer tablet with multiple coatings with an inner layer not containing active substance, thus modulating the release profile (p3, paragraph 2 and 11; p4, paragraph 9). The formulation may contain calcium carbonate, citric acid as well as other acceptable excipients while the coating may consist of a diffusion limiting polymer, such as ethyl cellulose (p6, paragraph 10 and 11; p4, paragraph 4). Among suitable coloring excipients for preventing abuse are indigotine, yellow orange S, etc (p7, paragraph 3). A pellet may be formed from spherical granules as melts upon exposure to heat and the matrix forming excipients include carnauba wax, polymethacrylate viscosity increasing substance, such as microcrystalline cellulose, (p4, paragraph 2, 7 and 9; p6, paragraph 4 and 18).

4. Claims 1-6, 9-11,17,18, 21, 23-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuczynski et al. (US 5,866,164).

5. Kuczynski et al. (US 5,866,164) teaches of a composition comprising an opioid, an opioid antagonist and a high molecular weight poly(alkylene) or a poly(carboxymethylcellulose (abstract). An antagonist composition contains a

polyethylene oxide of 7,000,000 (or 3,000,000 to 15,000,000) molecular weight, naloxone and ferric oxide which is granulated, pressed and coated (column 2, lines 56+; column 8, line 16).

6. Claims 1-13,16-18 and 21-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Oshlack et al. (US 2003/0064099A1).

7. Oshlack et al. (US 2003/0064099A1) teaches of an oral dosage form of an opioid analgesic with reduced abuse potential due to the addition of an aversive agent, such as a bittering agent that provides burning or irritating effects (p1, column 2+). A gelling agent, such as microcrystalline cellulose or polyethylene oxide can also be used to reduce the absorption of the opioid analgesic through injection when the dosage form is tampered with (p2, [0021-0023]; p4, [0049]). Polyalkylene oxide molecular weights vary from 1,000,000 to 10,000,000 (p13, [0151]). The dosage form may be a sustained release form in a matrix with the aversive agents including peppermint oil, oil of bitter almonds, capsaicin, as well as those listed in the instant claims, (p2, [0031]; p3, [0044-0047]; p7, [0080]). Suitable controlled release tablets may be formulated from multiparticulate formulations, wet granulation that is compressed into a tablet or melt and may contain hydrophobic binders, such as carnauba wax (p7, [0081]; p8, [0099]; p9, [0110-0111]; p10, [0120]).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alaux et al. (WO/2000/033835) in view of the combined disclosures of Oshlack et al. (US 2003/0064099A1), Porter (US 4,175,119) and Miller et al. (US 5,849,240).

10. Alaux et al. (WO/2000/033835) teaches of a zolpidem or salt thereof controlled-release dosage form as well as that listed above. Alaux et al. (WO/2000/033835) does not teach of a capsaicin, emetic or neuroleptic containing form.

11. Oshlack et al. (US 2003/0064099A1) teaches of an oral dosage form of an opioid analgesic with reduced abuse potential due to the addition of an aversive agent, such as a bittering agent that provides burning or irritating effects as well as that listed above.

12. Porter (US 4,175,119) discloses a composition comprising emetine and a psychoactive drug to preclude death from accidental or intentional overdosage. If the composition is consumed in accordance with the prescription no emesis occurs (abstract). The formulation includes emetic chemical emetine hydrochloride and a neuroleptic drug, such as fluphenazine (column 3).

13. Miller et al. (US 5,849,240) discloses pharmaceutical dosage forms for sustained release that include analgesics, such as morphine, wax binders and neuroleptic, such as promethazine (column 3, line 5). The preparation of the particles includes pressed tablets or melt-pellitization to form agglomerates (column 1, lines 49+; column 4, lines 50-51; claim 19). Suitable hydrophobic carriers include carnauba wax having melting points between 45°C and 90°C and microcrystalline cellulose (column 5, lines 15-34).

14. At the time of the invention it would have been obvious to one ordinarily skilled in the art to combine the oral dosage form of Alaux et al. (WO/2000/033835) with the antiabuse formulations of Oshlack et al. (US 2003/0064099A1) or emetic formulation of Porter (US 4,175,119) to make a safe abuse-proof dosage form that when taken properly will not exhibit the emetic or bitter characteristic. The use of the neuroleptic rather than an opioid agonist would be obvious to produce an antipsychotic abuse-proof dosage form for treatment of schizophrenia or mood disorders. All of the disclosed formulations have similar excipients and coatings and would be considered interchangeable.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP
July 11, 2006

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER